The Formation of an Environmental Technology Verification (ETV) Drinking Water Systems (DWS) Center - A Discussion Paper

Overview

NSF International (NSF) in partnership with the U.S. Environmental Protection Agency (EPA) proposed the establishment of an Environmental Technology Verification (ETV) Drinking Water Systems (DWS) Center in May 2000. The EPA entered into a cooperative agreement with NSF on October 1, 2000 to form the ETV DWS Center. The concepts and ideas that originated in the past five years during the operation of the ETV Drinking Water Treatment Systems (DWTS) Pilot were used to develop the proposal for the ETV DWS Center. To form the most effective Center possible, it is essential to receive the drinking water stakeholders' opinions and recommendations on the ETV DWS Center's mission, scope and future.

The purpose of this paper is to provide drinking water stakeholders with a focal point for discussion about the ETV DWS Center (the Center) and its proposed scope of operations. NSF and the EPA are requesting comments and recommendations pertinent to the proposed scope, mission and future of the Center (see details on how to contact NSF and the EPA at the end of the paper). NSF will include all comments sent to NSF about the ETV DWS Center with the paper for a stakeholder meeting scheduled for June 2001. An announcement about the stakeholder meeting will be sent in April 2001.

Proposed Mission and Scope

The Center will continue the work begun in the Pilot phase and will improve and add new aspects to meet the needs of the drinking water community. The Center will continue to provide independent third-party verifications of the performance of drinking water treatment technologies for community water supplies. Performance verifications will be expanded under the Center to include all sizes of water systems and performance verification of water supply distribution components. The Center will conduct testing of commercially ready, private sector technologies to substantially accelerate the entrance of new environmental technologies into the domestic and international marketplace.

Consistent with the ETV policies and strategy, stakeholders will play a key role in the development of the Center by providing guidance for the Center's activities. The stakeholders' primary functions are to assist in developing policies and procedures, prioritizing types of technologies to be verified, and implementing outreach activities to their respective constituents. The Center will provide the stakeholders with test protocols and product verifications along with information on the drinking water market, e.g., drivers or forces, changes in new regulations and emerging water quality issues.

<u>Center Objective #1: Enhance Quality of ETV Products</u>

A primary goal for the Center is to assure and enhance the quality of the ETV testing and evaluation, leading to reports and verification statements by consistent adherence to the EPA ETV processes, procedures, and approved quality management plan (QMP). NSF has an EPA-approved QMP that adheres to the ANSI/ASQC E-4 Standard on Quality and will continue to

improve quality through its quality management system. The Center will enhance quality through the process of continuous improvement based on the lessons learned during the five years of the pilot phase. With the EPA's Science Advisory Board's (SAB) recent recommendations (Appendix A) for even greater quality in all ETV programs, the Center will implement these recommendations with guidance from its stakeholders.

The EPA's "Environmental Technology Verification Program Quality and Management Plan for the Pilot Period (1995 – 2000)" requires more rigor in the testing, data management and reporting than originally envisioned in the pilot. Although NSF adapted its existing QMP to accommodate the ETV requirements and received the first EPA-approved QMP for the ETV pilots, many problems with the Field Testing Organization (FTO) system recommended by stakeholders arose during the pilot phase.

The FTO system under the ETV DWTS pilot involved the qualification of organizations to conduct testing. The EPA and NSF observed many challenges and obstacles with the FTO system during the pilot phase. The approval of some organizations to become a qualified FTO was based on the experience of a few of their key personnel. In actuality, these key personnel were not significantly involved in the planning of the ETV testing or report preparation. FTOs' use of inexperienced staff to write theses critical documents reduced their initial quality. The initial draft of the documents would contain numerous errors such as missing information, incorrectly transcribed data, inappropriate formatting, or poor explanation of aberrant results. This in turn meant that the turnaround time for these documents was slow due to multiple reviews and revisions of the same documents. Other quality issues with FTOs included insufficient human resources, inadequately trained staff, and the setting of ETV work as a low priority in competition with other work. *The present FTO system needs to be <u>seriously</u> revised to assure quality products in a timely manner.*

The Center must also collaborate with the stakeholders in meeting the recommendations of the EPA's SAB for data quality objectives. The Center must find a way to accommodate the EPA's requirements and those of the Center's stakeholders, relative to quality, cost and utility of the ETV protocols and testing.

In this regard, the second part of this objective is to improve existing ETV protocols and Test Plans. The Center will revise existing protocols from the lessons learned during the pilot to make them more cost efficient while improving their overall quality. Under the present ETV DWTS pilot, protocols and generic test plans were developed by experts and reviewed by stakeholders with validation occurring concurrent with verification testing. A critical part of the proposal for the Center is to update these protocols and generic test plans and to validate any new generic protocol or test plan.

<u>Center Objective #2: Increased Number of Verifications</u>

Another primary goal of the Center is to develop additional ETV reports and verification statements to satisfy stakeholder demand. The ETV DWTS pilot's original scope was to conduct testing of packaged or modular treatment systems that have easy plumbing and electrical connections. The Center envisions broadening the scope to include treatment components and

distribution system products. Another way to increase the number of verification statements and reports is to develop more partnerships to account for the decreasing funding by the EPA.

The Center will develop protocols for other drinking water treatment systems or infrastructure components such as adsorptive media, operation and maintenance devices (UV sensors and alarms, in-line membrane integrity sensors) or pipe rehabilitation technologies. This will allow for the performance verification of these products that the market will likely support. Most of the component verification testing will likely be performed under controlled laboratory conditions rather than in the field as was done in the ETV DWTS pilot. This is expected to improve quality control and save time in the production of verification statements and reports.

The Center will explore more partnerships with other organizations that value the quality provided by the NSF and EPA ETV oversight. These partners will be willing to help fund the testing while NSF assures the verification follows the ETV process. Although some limited partnerships were explored during the pilot phase, the Center proposes to explore others more assertively. A critical means of accomplishing more partnerships is to communicate the benefits of ETV verification to potential partners, e.g., public and private water utilities, state-funded laboratories, the EPA's Technology Technical Assistance Centers (TTACs), and vendors.

Another potential cost-effective way to increase the number and variety of verification statements and reports is to explore the use of existing data for both new verification reports and verification statements or revisions to verification reports and verification statements. During the ETV DWTS pilot, this option was initially explored but deferred as testing activity began to increase. In the interim, the ETV Program developed a policy ("The ETV Program Quality and management Plan for the Pilot Period (1995 – 2000)") that allows for the limited use of existing data in a verification report. NSF reviewed the ETV existing data policy and provided an interpretation (Appendix B) that only allows existing data be added to a verification report that was generated through ETV testing. Upon closer examination of the ETV existing data policy, it may be possible to use existing data as the sole basis for a verification report under the Center: " Compelling arguments exist for considering using certain *qualified* existing data to replace some or all of the verification testing for a given technology." The Center is seeking stakeholder advice regarding the use of existing data in the development of verification reports and statements and to clarify the present existing data policy.

The Evolving Drinking Water Condition

One of the many goals of the ETV DWTS pilot was to provide small communities with the tools to select products that have demonstrated their performance through credible third-party testing using a protocol developed through a broad stakeholder process. It was initially thought that small communities would have little problem with attaining appropriate treatment technologies. Unfortunately, the equipment is usually too expensive or complex to be feasible. Small communities, therefore, must use their resources wisely when selecting products.

An overall goal of the EPA's ETV Program is to streamline the regulatory approval process for the product manufacturer. Today, drinking water treatment manufacturers must seek approval for their system to be installed on a state-by-state basis. In many cases this process involves repeat testing, increased costs and delays in bringing new technologies to the market. The ETV

DWTS pilot provided for a consistent means of product testing. A state drinking water agency must also assure that the equipment will work as designed for a long period of time and is capable of meeting both the existing, as well as proposed, regulations. The ETV DWTS pilot was developed to provide the states with credible and quality data on the performance of drinking water treatment technologies including operation and maintenance information.

The state drinking water regulators are very supportive of the DWTS pilot and are eagerly waiting to see more verification reports and statements before fully committing to the reduction in site specific tests, such as for equipment used to treat primarily ground water contaminants. The Association of State Drinking Water Administrators (ASDWA) surveyed its membership in the fall of 1999 and 2000 about the ETV DWTS pilot (Table 1-1). The survey shows support by the states of the ETV DWTS pilot and the states will continue supporting the Center if it meets their expectations.

Initially, the vendors were cautious of fully committing financial resources to participate in a program in which regulatory relief is not yet guaranteed or at least costs are more easily quantified versus benefits. However, the number of products tested under in the ETV DWTS pilot rose each year. In response to the solicitation efforts in FY97 and FY98, three vendors submitted applications by the end of FY98. In March 1999, a second announcement regarding the availability of funding for testing expenses was issued along with a deadline of June 30, 1999 for applications. Seventeen applications were received and approved in response to this announcement. In July 1999, a request for notification from interested vendors with disinfection by-product precursor removal, arsenic removal, nitrate removal, and microbiological inactivation technologies was issued to assess the market demand for verification of these technology categories. Ten responses were received.

In 2000, vendors participated even though the amount of matching funds for testing decreased. Twelve more vendors expressed interest in verification testing as a result of the Request for Technologies issued in November 2000. These vendors expressed interest in verification testing even though the ETV matching funds have decreased since the inception of the pilot. This suggests the perceived value of the ETV DWTS pilot verification is beginning to increase.

ETV Operating Principles Influence the Center

The Center is required to operate according to the EPA's ETV operation principles. There are ten operating principles of the Environmental Technology Verification (ETV) program:

1. Performance Evaluation Goals
2. Commercial Ready Technologies
3. Third-Party Verification Organizations
4. Pilot Phase
5. Pilot Technology Areas
6. Stakeholder Groups
7. Pilot Evaluation And Program Decisions
8. Private Sector Funding
9. Outreach And Information Diffusion
10. Market Gap Definition.

Table 1-1. Annual State Survey Results - 2000

1) Are you familiar with the EPA/NSF Environmental Technology Verification Pilot for Package Drinking Water Treatment Systems?
   a) 35 – yes (28 in 1999)
   b) 1 – no (4 in 1999)

2) Do you intend to use the EPA/NSF ETV Standard Protocols and Test Plans for verification of package drinking water treatment equipment performance?
   a) 30 – yes (23 in 1999)
   b) 5 – no (3 in 1999)
   c) 0 – maybe (1 in 1999)

3) If you answered yes to question #2, how will you use it?
   a) 23 – reference EPA/NSF Protocols as method for site specific testing. (20 in 1999)
   b) 0 – require testing to EPA/NSF Protocols in state regulation. (3 in 1999)
   c) 0 – require testing to EPA/NSF Protocols in state codes. (1 in 1999)
   d) 0 – require testing to EPA/NSF Protocols in state legislation. (0 in 1999)
   e) 12 – other ways (9 in 1999): Policy (3 states); use as a supporting document; state guidance as a method for testing; in permit process; to consider data derived from testing; as a reference for developing testing programs; to waive on-site demonstration of performance; to demonstrate that a package treatment plant is acceptable for a specific application; as a resource material.

4) How will you use the EPA/NSF ETV Reports and Summaries?
   a) 27 – as a primary source of information upon which to base a decision. (19 in 1999)
   b) 12 – prerequisite to consideration of the technology. (16 in 1999)
   c) 4 – as a time saver when processing permits. (6 in 1999)
   d) 7 – other ways (6 in 1999Consider them as one method of verification (2 states); as a guide to site specific piloting requirements; as a supporting document; as a demonstration of the technology's efficacy, as a source of information upon which to base a decision; to reduce the length of any pilot studies.

The ETV DWTS pilot fully addressed principles 1 through 6 and 9, and touched on some of the remaining principles. The DWTS pilot is completing the evaluation phase (#7) that includes this paper as part of the evaluation. The Center plans to operate according to the respective ETV principles beyond the scope of the Pilot Phase.

The following discussion is designed to help the ETV Center meet the remaining principles of operation. The discussion in this paper will focus on the following:

- Establish an ETV Center with a focus on Drinking Water as the outgrowth of the pilot evaluation and outreach, i.e., communication, to support the Center's growth;
- Enhance quality through process improvements, especially the FTO system and protocol modifications; and
- Increase the number and scope of verifications through development of new protocols based on stakeholder need and market assessment and also enhance private sector funding of some Center activities.

Develop a Drinking Water Systems (DWS) Center

As previously stated, the primary goal is to form an ETV DWS Center for the verification of new, innovative and emerging drinking water systems technologies. This is critical to meeting the ETV operating principle of defining and filling market gaps. The first step is complete – the formation of the Center through an EPA grant to NSF. The next step is the promotion of the Center and its mission as well as re-defining, as necessary, its scope. In addition to complete package treatment systems, the Center's scope will include performance verification of other drinking water treatment systems or infrastructure components such as adsorptive media, operation and maintenance devices (UV sensors and alarms, in-line membrane integrity sensors) or pipe rehabilitation technologies. With a wide coverage of products, the Center will attract interest by a broader group of vendors that will enhance the Center's potential viability and self-sufficiency. This is critical to meeting the ETV operating principle of private funding of testing.

The effort for outreach and communication will focus on promotion of the DWS Center to all stakeholders. However, the effort will be greatest towards the stakeholders who, by their support, will accelerate the private sector development. The Center already has considerable support from the states through ASDWA. However, this high level of support, albeit important at the highest level, e.g. administration, must also occur at the senior technical and middle engineer levels as well. The Center plans to continue to offer free workshops to state engineers at their location. The "go to them" strategy is expensive but effective in the widespread dissemination as the workshop approach uses a frank question and answer approach. The objective of the message for states' support will remain:

- Encourage the use and requirement of ETV protocols and test plans for in-field performance verification testing as a minimum,
- Encourage the acceptance of ETV protocols and test plans involving laboratory testing,
- Promote the credibility and independence aspects of the Center, and
- Share information from the annual ASDWA survey on how their colleagues are using ETV products especially in decision making.

Communication will also be directed at users (water utilities and other government agencies)

especially those most likely to have funding available for verification activities. The best way to reach the large water utility administrators is through exhibits at the annual conferences. The Center will also request meetings with numerous federal agencies that have expressed interest in ETV and presentations will consist of a workshop-type forum similar to presentations given to the states under the pilot phase. Target audiences include the Department of Defense (DOD), especially the U.S. Navy, the Center for Disease Control (CDC), and U.S. Department of Agriculture (USDA) Forest Service.

NSF's association with the World Health Organization (WHO) Collaborating Centre creates the potential for WHO recognition of the ETV methodology for verification and a system for the promotion and dissemination of the ETV Program to the international drinking water community. Such a relationship between the Center and the NSF WHO Centre will enhance the acceptance, i.e. possible adoption, of ETV verification protocols and test plans in WHO Guidelines. The relationship will also:

- Encourage foreign governments to adopt the ETV DWS Protocols—thus working toward international consistency in testing requirements.
- Encourage foreign manufacturers to obtain performance verification.
- Assist WHO/United Nations (UN) efforts to access reliable technologies (e.g. Arsenic treatment and analytical technology) to assure availability of proven technologies for relief efforts.
- Establish formal information dissemination through regular symposia/workshops for manufacturers, regulators, and users.

Finally, the Center will hold annual vendor meetings to solicit support and gauge market interest. The Center will hold these ETV vendor meetings near the same time as at the same time as the annual Steering Committee meeting. At the meeting, the Center will explain how vendors can become involved and arrange for testing, and discuss potential sources of funding (funding database). The Center will give FTOs the opportunity to exhibit at the meetings as well, in order to attract interested customers.

Verification Process Improvements

The verification process requires modifications and improvements in order to meet the EPA's quality objectives for the Center. The areas identified during the DWTS pilot phase as needing improvement were:

- FTO system approach,
- Better use of laboratories and specialists,
- Field Operations Document (FOD) review process,
- Report preparation, and
- Protocol development and maintenance.

<u>FTO System Approach</u>

The FTO system under the ETV DWTS pilot involved the qualification of organizations to conduct testing. The EPA and NSF observed the following challenges and obstacles with the FTO system approach during the pilot phase:

- The approval of some organizations to become a qualified FTO was based on the experience of a few of their key personnel. In actuality, these key personnel were not significantly involved in the planning of the testing, which resulted in delays as the FTO submitted multiple (>3) revisions of the FOD for review. It was also observed that these key individuals were not significantly involved in the ETV report writing phase either. The turnaround time of reports and verification statements was slow as a result of the FTO's use of inexperienced staff to write the ETV report. Again, the FTO would submit multiple revisions of a poor quality report including missing information, incorrectly transcribed data, inappropriate formatting, or poor explanation of aberrant results.
- In several instances, FTOs were unable to complete the work in a timely manner. Delays in the completion of the verification work were attributed to insufficient human resources, inadequately trained staff, and from setting the ETV work as a low priority in competition with other work.
- Qualified organizations that have expertise in only one specialized area of testing (e.g., microbiological seeding studies) did not meet all of the qualifications to become a NSF-qualified FTO. To participate in the ETV DWTS pilot, they had to be a subcontractor to a qualified FTO and this resulted in more expense from overhead and less direct accountability to NSF, the EPA and its ETV Program. Little or no direct leverage could be applied on these expert subcontractors to complete work expeditiously as NSF had no direct contract with the experts.

Since the stakeholders had embraced the FTO system approach during the organizational stage of the DWTS pilot, it will not be completely abandoned. However, major changes must be implemented to facilitate more accountability and address the challenges that arose during the pilot.

The Center proposes to alter the FTO approach so that it is more accountable (timely and responsive) and pro-active (meet the new ETV data quality criteria and prevent errors). To satisfy the EPA ETV Program's quality needs, some of the relationships of the parties involved must also change. One option that was successful during the last two verification tests during the pilot phase (testing UV products) was NSF actively managing the relationship between vendor and FTO. This active management where vendors contact NSF directly for assistance was proposed at the January 1999 stakeholder meeting. The pre-test activities (cost discussions, FOD preparation, etc.) for the testing of UV products were very successful suggesting that the option of NSF managing the vendor-FTO relationship should be reconsidered as another option to the present FTO only approach.

The Center plans to address the concern that some FTOs became qualified based on the experience of a few key personnel, who later were not involved significantly in any ETV activity, by requiring that all previously qualified FTOs submit an annual application to renew their status. When an FTO submits a renewal application to the Center for verification testing, the FTO must explain in the application who will manage and direct all ETV activities. This person shall be experienced in conducting the testing of drinking water systems and allocate a significant portion of their time, e.g., 25%, to the direct management, training, and supervision of the staff involved in verification testing. This commitment of the FTO's experienced staff will become part of the contract agreement with NSF. This approach was used successfully in the pilot phase when developing protocols and test plans.

The Center plans to address the concern regarding poor quality, (e.g. the submission of multiple revisions of documents with missing information, incorrectly transcribed data, inappropriate formatting or poor explanation of aberrant results) and lack of timely submission of reports and verification statements in a variety of ways. Although the basic criteria for qualifying an FTO recommended by stakeholders in 1997 will not be altered, there will be additional training requirements for both the first time FTO and all previously qualified FTOs. Before testing can begin, the FTO must receive a minimum of one training session on the requirements of ETV testing. The Center also proposes that any FTO or laboratory wishing to maintain their status as "qualified" to conduct work under the Center must have annual training on the EPA ETV QA/QC requirements in Center testing. Training may be accomplished several ways including, but not limited to, a seminar held at the Center, by telephone conference, or by a video conference call. In addition to the training proposed, the Center will begin assessing a fee for the review of FODs and verification reports upon receipt of the third draft from the FTO in which previous comments (not new comments) were ignored.

The Center will assess the FTO's annual performance based on the demonstration of quality in past verification activities that include:

- Timeliness in delivery of documents and conduct of testing (minimum delays in the start up of testing, few revisions of an FOD or verification report),
- Responsiveness by addressing and not ignoring review comments or ETV schedules, and
- Completeness (submittal of all quality control data) and accuracy (appropriate technical judgement based on technical review).

Any FTO that satisfies the above three criteria may have a reduced inspection frequency during verification testing. Most of the inspection expenses will be covered by the EPA agreement with the Center. However, the Center will inspect an FTO more frequently if the FTO does not satisfy the above criteria based on past performance. If more frequent inspections are required, the inspection costs incurred by the Center will be charged to the FTO as inspection fees. An FTO with unsatisfactory performance will also not be eligible to receive any matching funds under the Center until its performance is deemed satisfactory based on inspections, training and document reviews. An FTO with an unsatisfactory performance may be reclassified as "conditionally" qualified. Continued unsatisfactory performance by the FTO will result in disqualification by the Center.

The Center will select an FTO with repeated demonstrated high performance to conduct ETV protocol validation studies. A protocol validation study typically will involve verification tests (against previously untested protocols and/or test plans?) that require more ETV matching funds than the normal amount proposed under the operation of the Center. Demonstrated high performance will be determined by the timeliness, responsiveness, and completeness previously discussed.

Laboratories and Other Specialists

Partnerships developed to enhance private sector funding during the pilot phase had limitations with meeting the ETV quality control requirements. Although laboratories were either EPA-approved to conduct analysis for *Cryptosporidium* under the Information Collection Rule or

state-certified for enforcement monitoring, many of these laboratories were unaccustomed to and unprepared for the rigors of the quality controls required under the ETV DWTS pilot. Often, these laboratories reported only final results with no bench sheet or formulas for calculating the reduction of microorganisms.

To prevent quality limitations in the Center's testing reports, such as not analyzing duplicate and spiked samples in the same batch as ETV samples, the Center will require the training of the laboratory and specialists before they begin ETV testing. The Center will offer mandatory training on the QA/QC requirements in Center testing for laboratories wishing to maintain their status as qualified to conduct work under the Center.

To address the need to use the talents of specialist organizations in a more accountable fashion, the Center proposes to have a direct contractual relationship with these specialists, including laboratories, as NSF presently has with FTOs. With a contract, the Center will have more direct leverage on these specialists and laboratories to complete work expeditiously. For laboratories and specialists not presently certified for specific analyses, i.e., *Cryptosporidium* enumeration, the Center will develop criteria for becoming qualified to do special analyses. The specific criteria will be developed with stakeholder input.

To make these partnerships work better in the future and continue to stride toward the quality objectives of the EPA, the Center proposes to modify the existing verification process as follows:

- All laboratories interested in participating under the Center will be required to undergo training on ETV QA/QC requirements before testing begins. The training will involve NSF staff.
- The Center will also require a meeting (by telephone call or in person) between NSF, the laboratory, and FTO personnel. The Center will provide staff to train laboratories and specialists on special QC requirements.
- Laboratories demonstrating repeated high quality may be exempt from the mandatory training. .
- The laboratory will be required to attend a verification test-planning meeting with the FTO for the first time the two organizations have worked together on an ETV project.

The Center will apply NSF's process of managing subcontract laboratories to work performed under the Center. The specific actions proposed include:

- The laboratory or specialists shall have a state certification, EPA approval, or be independently assessed by NSF for the parameters they will perform during verification testing.
- In some cases, NSF may assess the quality processes presently practiced by the organization and determine the organization's readiness to perform the work under the ETV program. This "readiness" audit process will be developed less stringently than an accreditation audit, however it will be more an assessment of the typical quality control documentation practices and whether their facility is properly equipped to conduct the specified work.
- Once approved to perform the work, the laboratory must provide the Center with QC data. NSF's QA Department will review the QC data for the ETV related work and report results to the Center's Project Engineer.

Field Operations Document Review Process

One lesson learned in the pilot phase was that effective oversight of verification testing includes a team-based approach to the review of the FOD, which contains the detailed procedures for the verification testing.

Under the Center, the DWS staff will use a multi-disciplinary team review as part of the FOD review process. Experiences to date have shown that a multidisciplinary team approach works well in assuring the quality of verification products. NSF began implementing the use of its independent QA officer and other specialists, such as NSF microbiologists, in successfully conducting FOD and report reviews during the final two years of the pilot. With this approach to FOD reviews, the Center hopes to identify potential issues that can be resolved earlier in the planning phase rather than during testing.

The modified process will include leadership from the NSF Project Engineer who is responsible for the review of the equipment setup, configuration, and experimental design (general conformance to the ETV protocol). This means that at a minimum, NSF's QA officer will review the QC portion of an FOD and that another NSF staff member will provide a technical review along with the NSF Project Engineer's review of conformance of the FOD to pertinent protocols and technology test plans. The Project Engineer may include in the team a senior chemist (inorganic or organic), microbiologist, laboratory accreditation auditor, and water quality specialist based on the requirements of the protocol and test plan. When necessary, NSF will retain outside experts to assist with the FOD review such as to supplement areas of staff limitations.

Finally, NSF found useful the comments of an extramural technical reviewer for first time use of an ETV DWS Center protocol and technology specific test plan, during the pilot's arsenic validation study. NSF proposes to always use an extramural technical reviewer of an FOD based on the first time application of a protocol or technology specific test plan. In some cases, the EPA will provide this review.

Report Development Process

During the pilot, the time to develop a report after completion of testing was too long. Last year, 11 verification reports and statements were issued. Report writing, which is measured from the date that testing is complete to the date that the verification statement is issued, required from 4.5 to 16.5 months. The average amount of time was approximately 10.8 months. NSF and the EPA identified two areas of the process that if changed could result in both higher quality reports and quicker report development: 1) the writing of the report by experienced personnel, and 2) the review of reports by a multidisciplinary team.

One key lesson learned from the DWTS pilot was that the use of experienced personnel in the development of the reports created credible and well-written reports. As discussed previously, NSF observed in the pilot phase that sometimes relatively inexperienced personnel, and not those referenced in the FTO's application, were actively involved in the field collection of data, and writing the report, with no review by the key qualified personnel listed in the FTO's application. A common result was a very poor quality report. For example, reports were submitted with results in the midst of a section describing the methods and procedures and reviewers' comments were ignored for many reasons (e.g. not understood, does not know how to address the

comments, too little time). Many FTOs were ill prepared for the rigorous documentation and explanation required in an ETV DWTS pilot report.

During the pilot, NSF tried to hasten the verification process and the report preparation process specifically by modifying the work orders of the FTOs so that payment was contingent upon successful delivery of work products in stages. NSF has even withheld payment until the milestones were met. This financial incentive approach had mixed results. The small business type FTO would be very responsive to these payment milestones, but universities and relatively large organizations were unresponsive.

NSF also took a pro-active measure by sending the FTOs an electronic copy of a typical ETV report with standard ETV introductory language, format, and section headings followed by instructions on what should go in each section. This has helped with the conscientious FTO eager to receive payment, but was at times ignored by other organizations.

Although during the pilot NSF tried many management approaches to accelerate the report preparation, the quality of reports and turnaround time was often not affected by these approaches. The EPA and NSF decided there was a need for more fundamental changes in the process. The Center plans to require in the contract with FTOs, laboratories and specialists, that the key personnel, upon which the organization was qualified by the Center, will either write the report or allocate a significant portion of their time, e.g., 25%, to verification reporting oversight or review. An acceptable alternative is a Quality Management System wherein the FTO assures the quality in the report preparation process.

The EPA identified areas to improve in NSF report review process. Experiences to date have shown that a multidisciplinary team approach works best in assuring the quality of a verification report review. NSF implemented the use of its independent QA officer and other specialists, such as the NSF microbiologists, in successfully conducting the report review during the later period of the pilot. The Center will implement a change in the report review process where instead of a single person reviewing the report, a multi-disciplinary team will review it to identify more QA issues that can be resolved earlier in the report preparation phase. The NSF Project Engineer will identify the other internal NSF expert reviewers for the team review such as a senior chemist (inorganic or organic), microbiologist, laboratory accreditation auditor, water quality specialist, the QA officer, or the Manager based on the requirements of testing. In all cases, the review will involve at least the Project Engineer, the NSF QA Office review of QC data, and an internal expert. NSF will continue to retain outside experts to assist with the technical peer review. Results to date have shown that an outside expert reviewer has been valuable during the report preparation process.

Protocol Development and Maintenance

NSF has catalogued many lessons learned during the pilot phase that will be used to update and revise the existing protocols and test plans. During the pilot phase, generic protocols and test plans were developed and then used for testing before any validation study. Both the FTOs and the EPA identified numerous technical issues and concerns with the protocols that resulted in either testing delays or unnecessary cost expenditures. Some examples are:

- A requirement to calibrate turbidimeters with standards that do not exist for the range of turbidity typically found in drinking water, or they are not appropriate for the instrument.

- The determination of an acceptable method or procedure of obtaining data when a specific Standard Method does not exist for the measurement of that contaminant.
- Clarification regarding what is expected with three replicates and the employment of a capture filter within the scope of membranes for reduction of microbiological and particulate contaminants.
- Ordering a specific size of a microsphere for a microsphere-seeding task that is not readily available or standard in the microsphere industry. Special ordering the microspheres delayed a test by three months during the pilot phase.
- Use of EPA Methods 1622 and 1623 should require the use of *Giardia Lamblia* because these methods are not conducive to the use of *Giardia Muris.*
- Frequency or number of samples required for key parameters were insufficient to meet data quality objectives and verify performance claims.

To address the issue of unforeseen technical issues with newly developed ETV protocols and generic test plans, the Center proposes to validate each new protocol or test plan with a validation study. The Center also recommends validation studies for any ETV protocol or generic test plan that has not yet been used in testing. These recommendations are contingent upon available funds for validation studies and the priorities of the Center's stakeholders for which protocols should be validated.

The Center also proposes a process for maintaining existing ETV Protocols. The process proposed is inherently quicker than the development process used in the pilot phase:
- Center staff will review technical issues submitted by FTOs, the EPA, and other stakeholders with technical experts and propose modification(s) to the ETV Protocol.
- Proposed modification(s) of the ETV Protocol will be announced and made available on the Center and EPA ETV web sites for review and comment.
- All germane comments with the proposed modification(s) will be forwarded to the Steering Committee for recommendation or modification.

Summary of Verification Process Improvements
The quality assurance paradigm under the ETV DWTS pilot was developed in conformance to ANSI/ASQC Standard E-4 with a pilot specific QMP. NSF readily adapted its existing QMP to accommodate the ANSI/ASQC E-4 Standard on Quality, and received the first approved QMP for the ETV pilots. For the formation of the Center, the new quality paradigm is continuous improvement towards the best quality with the consensus of the drinking water stakeholders. This continuous improvement paradigm has worked well during the pilot phase and will be continued in the Center.

The Center proposes to modify verification processes and procedures to meet challenges and obstacles to quality objectives observed during the ETV DWTS pilot as described in the previous sections concerning verification testing and protocols. Although specific quality changes were presented in previous sections, the following list summarizes the major improvements to be immediately implemented during the formation of the Center:

- The process of developing a protocol and test plan, especially their QC requirements, will be modified to involve more review of experts in quality assurance, the EPA, and NSF QA

officers. The Center expects the process to result in the evolution of protocols and test plans with more quality requirements.

- The Center will most likely improve these processes: test planning (FOD preparation), verification testing, qualification of FTOs and laboratories, report preparation, and review of ETV documents.
- A more pro-active approach will be used whenever possible throughout the process to prevent errors and omissions. There are several mandatory training requirements proposed to assure all participants in ETV testing fully understand the quality requirements in the verification process, protocols and test plans.
- Qualification of FTOs will be modified to enhance the use of more experienced staff. More experienced staff involved in the testing and reporting operations will help to prevent poor coordination, missed QC reporting, misunderstanding of the effort involved in documenting QC, and delays from multiple submissions of documents.
- Senior NSF staff from multiple disciplines will augment the review of ETV documents from the test planning stage to the report phase.
- The Center will require mandatory meetings or training on the ETV quality documentation and specific testing requirements between NSF staff or team, the FTO, laboratory, and specialists. The purpose of the meetings will be to ensure collaboration and communication between those involved in the testing to assure that quality objectives are met.

Enhance Private Sector Funding Support

"Private Sector" includes any source of funding or activities that can be leveraged to offset the need for ETV funding of testing including in-kind services. Private funds may originate from any number of sources including the vendors, government, and private entities other than the EPA such as a water utility, DOD, U.S. Navy, USDA, states programs, etc. One goal of the Center is to maximize the use of private and other sources of funding and to minimize the use of EPA's ETV funds for testing without jeopardizing the quality of ETV products and services or stakeholder support.

The topics covered under this section will focus on how other funding sources will help establish the DWS Center, enhance its credibility in the drinking water community, and stride towards self-sufficiency in the market place. The discussion on the private sector funding is based on the ETV Program's vision of future activities. Currently the ETV program envisions that the Center will using EPA ETV funding the following activities fully:

- Stakeholder process,
- Protocol and generic test plan development, and
- Program outreach.

The ETV Program's preliminary view is to fund a portion of these activities:

- Quality assurance and quality control (document reviews, data reviews, inspections), and
- Report writing.

The ETV Program has the preliminary view that the private sector will fund the following activities:

- Testing,
- Data analysis (majority of the report writing), and
- Product outreach.

The following sections describe how the Center will meet this vision of increasing private sector and decreasing ETV funding for its activities.

Partnerships

During the pilot phase, NSF explored some limited partnerships. Partners with the DWTS pilot included water utilities, state-funded laboratories, the EPA's TTACs, and vendors. The partnerships were, for the most part, successful and provided the basis of future partnerships with the Center.

In the present market environment, water utilities, especially medium to larger utilities, have historically provided most of the funding for in-field pilot testing. In the ETV DWTS pilot, water utilities often provided in-kind services, such as sample collection and laboratory analysis. Some examples include the City of Pittsburgh's laboratory that conducted laboratory analysis, including chemical analyses and enumeration of *Cryptosporidium* oocyts, and the community of Barrow, Alaska, that collected samples and conducted on-site physical and chemical analyses.

There has been some initial success with the EPA's TTACs that were specifically authorized by Congress under appropriation bills to assist small communities. In one partnership involving the University of New Hampshire (UNH), a qualified FTO and TTAC, and the University of Alaska at Anchorage (another TTAC), TTAC funds were made available for the non-ETV specific activities such as demonstration testing. ETV and vendor funds covered ETV specific activities, such as FOD development and the report preparation. This particular partnership was very timely, met quality objectives, and was cost effective.

Other federal agencies have contacted NSF and expressed interest in supporting the ETV DWTS pilot. They include the CDC, DOD, U.S. Navy, and the USDA Forest Service. So far, no partnerships have been formed. However, the Center will foster the interest by these agencies. The Center will solicit support and funding from other federal and international agencies.

Vendors have participated in the DWTS pilot by providing equipment for verification testing and funds, both cash, out-of-pocket, and in-kind expenses. Before the ETV DWTS pilot, the expenses they typically paid were for out-of-pocket costs such as for laboratory analytical testing. Vendors are now participating with significant investments of time and money in the ETV DWTS pilot. With the EPA ETV matching funds, vendors' typical out-of-pocket expenses range from $5,000 up to $45,000 with a median expenditure of $21,000.
During the most recent verification testing, vendors are contributing a minimum of $25,000. With the market value of verification reports and verification statements increasing, it appears vendor contributions will continue to increase, but to what maximum amount is yet to be determined.

Database of Alternative Testing Funds

With limited or no funding available from the ETV Program for testing, vendors interested in receiving a verification report and verification statement need to know what alternative sources of funding are available to cover most of the testing costs. The present market conditions do not yet favor coverage of all testing costs by the vendor and therefore the Center proposes to contribute report preparation funding by approximately $25,000 per test. The actual amount would be determined by the Center's finite budget and market demand from an annual Request for Technologies announcement.

The Center is seeking the recommendations of its stakeholders on whether to maintain a database of possible sources of testing funds. If the database concept were recommended, it would likely include a record of:

- Private water utilities that plan to fund their own testing and demonstration of technologies,
- Public water utilities that have contacted NSF about verification testing and have some funding or in-kind services available for testing, ,
- States that set aside revolving funds for small systems for a certain fiscal year (this will require considerable advance communication with state administrators),
- DOD Agencies such as the Navy and the Army based on the present Memorandum of Agreement between the EPA and DOD for the ETV and the Environmental Security Technology Certification Program (ESTCP),
- Other agencies with specific needs such as national parks under control and supervision by the Forest Service of the USDA or the CDC in their supervision of the Vessel Sanitation Program,
- Foreign nations, such as India, that under agreements with the EPA and the ETV program may be other sources of funding for testing. Such work must be coordinated through the ETV Program Office,
- Banking institutions interested in funding small businesses with venture capital will also be listed as a resource, and
- Research foundations or centers (EPA TTAC) that have an interest in funding testing of ETV Projects.

The database will include but is not limited to the following items:

- contact person,
- location (US Postal and Internet),
- telephone and/or facsimile number,
- technology areas of their interest or if unknown, water quality issue to be resolved,
- range of or the maximum funding available (optional, as many may not want to commit publicly),
- special role or conditions such as a minimum cost sharing by the vendor, and
- the role that ETV will play with each group.

Existing Data

In the early years of the ETV DWTS pilot, the use of existing data was a very important issue to both the states and vendors. However, no final agreement was reached among the stakeholders

on the acceptable amount of quality control and how to use existing data in the DWTS pilot phase.

In the interim, other events made existing data a moot point of discussion. First, a considerable amount of seed money became available to the DWTS pilot in its second and subsequent years to supplement testing costs. Next, the DWTS pilot met with stakeholders about the cost of testing that limited involvement even with supplemental funding. At the stakeholder meeting held in January 1999, states agreed that the DWTS pilot should specify a minimum of one period of testing in all the ETV protocols rather than four seasons of testing that were being required in a majority of the protocols. The stakeholders also agreed that verification reports and verification statements could later be modified to include new data with testing conducted at later times (seasons) and at different sites (range of water quality). With this recommendation, testing began in earnest and existing data criteria development was no longer discussed.

New events lead the Center to expect that existing data will become increasingly important in the development of new verification reports and verification statements and the issuance of revised verification reports and verification statements. First, the states are requiring and using ETV DWTS pilot protocols for the conduct of site specific testing (Table 1-1). NSF developed a procedure for the existing data review process that followed the ETV QMP. A summary of the existing data review process and how to proceed with submitting existing data for review is presented in Appendix B.

In an effort to foster privatization, the Center is requesting its stakeholders to review and comment on the ETV Existing Data Review process. Stakeholders need to address these questions and concerns:

- Assess whether the process based on ETV policy is acceptable for development of an original verification report and verification statement and not merely a modification to an existing verification report and verification statement.
- Should there be different processes or acceptance criteria for data used in the modification of an existing verification report and verification statement?
- Should operation and maintenance data have different evaluation criteria and data quality acceptance than physical, chemical and microbiological data?

Since the states are using the ETV DWTS pilot protocols and test plans for use in site-specific testing, existing data will be a key part of the Center's future activities. Also, stakeholders may find the existing data option is a way to address concerns about how well vendor equipment performs under a range of conditions. Although existing data review has the potential to satisfy many demands in the future of the Center, its expense will most likely be borne completely by non-federal ETV funding sources.

Priorities for New Protocols

The Center expects that new protocols and test plans will need to be developed as stakeholders, especially states and the EPA Office of Drinking Water and Ground Water, have asked the ETV DWTS pilot to provide more information on treatment components and operation and maintenance devices. Depending upon the budget and market interest, the Center will develop new protocols for technologies such as the following:

- In-line particle counters as indicators of loss of membrane integrity,

- UV sensors and alarms to warn operators of the loss of disinfection,
- Adsorptive media for removal of arsenic, other inorganic chemicals, Methyl Tertiary-Butyl Ether (MTBE) and other organic chemicals, and
- Pipeline rehabilitation technologies to correct water loss, prevention of red water problems, and lead and copper corrosion prevention.

Although the budget for subcontracting services is limited, the Center will solicit market interest from a Request for Technologies, review of past inquiries in its files, and its present customer database. The Center will then solicit stakeholder input on the priority for protocol or test plan development based on public health and environmental considerations. New protocols and test plans will be developed where market interest and stakeholder priority overlap.

There is a high degree of interest in adsorptive media for arsenic and MTBE because new regulations are being developed for both of these chemicals. Consequently, the Center proposes to develop laboratory methods for verifying the performance and estimating the capacity of adsorptive media. In theory, testing could be conducted in a laboratory setting using an adaptation of the rapid small scale column test (RSSCT) rather than a lengthy field test as described in the present ETV protocols.

Finally, as the budget allows and as illustrated above with the adaptation of a laboratory method for a new purpose (RSSCT as a means to conduct testing of arsenic adsorption capacity), protocol validation studies will be performed for new protocols. The assumption under the DWTS pilot was that most protocols and test plans had minor difficulties and could be adjusted while conducting verification testing. This assumption was incorrect as errors were found in most protocols. Before new protocols become final under the Center, they will undergo a "validation" study to identify unforeseen difficulties and deficiencies.

Conclusion

The opportunities of the newly formed ETV DWS Center to assist the drinking water community are numerous. To achieve success, the Center's stakeholders need to provide direction to the EPA and NSF in the administration of the Center. Both the EPA and NSF look forward to stakeholder comments and recommendations both now and into the future.

Contact Information

Please send your public comments on this paper to:

Person: Bruce Bartley, Manager

ETV Drinking Water Systems (DWS) Center

NSF International

789 Dixboro Road

Ann Arbor, Michigan 48105

Email: bartley@nsf.org

Facsimile: 734/769-5195

NSF will include all comments sent to NSF about the ETV DWS Center with the paper for a stakeholder meeting scheduled for June 2001. An announcement about the stakeholder meeting will be sent in March 2001.

General Information about the DWS Center can be found on the NSF Web Site at www.nsf.org/etv/dws.

APPENDIX A:
Science Advisory Board Findings and the EPA's Response

EXECUTIVE SUMMARY

The Technology Evaluation Subcommittee of the Science Advisory Board's (SAB) Environmental Engineering Committee met March 6-8, 2000 in Washington, DC to review the degree to which quality management is incorporated into the Environmental Technology Verification (ETV) program. In this review, the Subcommittee considered the applicability of the ANSI/ASQC E-4 standard; Agency policy, requirements, and guidance; and the experience of the Subcommittee. Appendix A lists the documents reviewed by the Subcommittee including the ETV quality and management plan and quality documents for seven completed pilot studies. The latter included documents such as pilot quality and management plans, generic test protocols and technology specific Test/QA plans. Appendix B is a brief summary of selected documents in EPA's Quality System. Please note that, in this report, the Subcommittee has used the word "Agency" when describing Agency level activities and decisions, such as the Agency's Quality System, policies and requirements. The Subcommittee has reserved the words "ETV program" for decisions and activities within that program.

The Agency's Quality System and ANSI/ASQC E-4 consensus standard provide an effective framework within which the Environmental Technology Verification (ETV) program has established a multi-tiered quality assurance oversight system. In summary, the ETV program has effectively implemented major portions of the Agency's Quality System. ETV has made excellent use of stakeholder advisory groups in establishing technology specific verification factors acceptable to both users of and permit writers for environmental technologies. Because the stakeholder advisory groups have been beneficial, the Subcommittee suggests that the Agency capture its experience in the form of guidance on how future stakeholder advisory groups should be constituted and their specific role in verification test development.

The Subcommittee recommends that the Agency consistently employ a structured data quality planning process such as the Agency's DQO process (EPA QA/G-4) to develop generic test protocols and Test/QA plans. Use of a systematic data quality planning process ensures that the decision-maker's needs are appropriately considered in the development of verification testing procedures and in the reporting of verification test results. In this case, those needs include the environmental marketplace's requirements for a minimum technology performance standard and understanding technology performance variability

Finally, the Subcommittee was alarmed to discover that some ETV verification partners and their subcontractors are convinced that their ETV data collection activities are not subject to the same quality assurance requirements adopted by the Agency. The Agency's Quality System mandates that specific quality requirements be implemented whenever environmental data are collected for or on behalf of the EPA without regard to whether the data collection activity was funded under contract, grant, or cooperative agreement. Without this element of quality assurance, the future credibility of the ETV program is at risk. The Subcommittee therefore recommends that the ETV program enforce these requirements on all verification partners.

APPENDIX B: Existing Data Review Process

DRINKING WATER TREATMENT SYSTEMS ETV PILOT
APPLICATION FOR EXISTING DATA

The purpose of this procedure is to describe the process for consideration of an existing data package submitted under the Environmental Technology Verification (ETV) Project for Package Drinking Water Treatment Systems (PDWTS). The process is based on the ETV Program Policy Compendium and the EPA's Quality Management Plan.

A Field Testing Organization (FTO) or Manufacturer may request review of an existing data package of a Manufacturer's commercially ready PDWTS that is being tested and evaluated under the ETV project. Before submittal, the entity submitting the data package should review the package to ensure that it meets the minimum general acceptance criteria, as set forth below:

- The data meets the requirements of the ETV PDWTS protocol and test plan being used for evaluation tests of the technology. At a minimum, the existing data must meet the same level of QA/QC, replicate tests, data treatment, and reporting that is required for a verification report.

- The conditions under which the data were collected are clearly defined and were appropriate for the demonstration of the capabilities of the technology.

- Sufficient data are supplied to allow the technology to be evaluated. Sufficiency of the data will be determined by NSF and subsequently the technical reviewers.

- The data has been collected objectively and independently of the vendor.

Review of Existing Data under the ETV PDWTS project will be comprised of the following key activities:

- Identifying and Qualifying the Data by NSF,
- Convening a Data Evaluation Panel (DEP) by NSF,
- Evaluation of the Data by the DEP,
- Recommendations by the DEP for Acceptance of Data for Verification Report Supplement, and
- Review and Acceptance of Recommendation by NSF and EPA.

Existing data may not be used as the sole basis for a verification report under the PDWTS ETV. Existing data may be used to accompany testing results that are generated under the ETV and placed in the appendix of the ETV report if they meet the criteria described in this procedure.